

Physical Indicators

Heat sterilization

- In heat sterilization processes, a temperature record is made of each sterilization cycle with both dry and moist heat (i.e. autoclave) sterilizers, this chart/digital record forms part of the batch documentation and is compared against a master temperature record (MTR).
- It is recommended that the temperature be taken at the coolest part of the loaded sterilizer
- Further information on heat distribution and penetration within a sterilizer can be gained by the use of thermocouples placed at selected sites in the chamber or inserted directly into test packs or bottles.

Gaseous sterilization:

For gaseous sterilization procedures, elevated temperatures are monitored for each sterilization cycle by temperature probes, and routine leak tests are performed to ensure gas - tight seals.

- Pressure and humidity measurements are recorded. Gas concentration is measured independently of pressure rise, often by reference to weight of gas used.

Radiation sterilization:

In radiation sterilization, a plastic (often Perspex) dosimeter which gradually darkens in proportion to the radiation absorbed gives an accurate measure of the radiation dose and is considered to be the best technique currently available for following the radio sterilization process.

Filtration sterilization

Sterilizing filters are subject to a bubble point pressure test

▽ which is a technique employed for determining the pore size of filters,

- ▽ may also be used to check the integrity of certain types of filter device immediately after use.
- ▽ The principle of the test is that the wetted filter, in its assembled unit, is subjected to an increasing air or nitrogen gas pressure differential.
- ▽ The pressure difference recorded when the first bubble of gas breaks away from the filter is related to the maximum pore size.
- ▽ When the gas pressure is further increased slowly, there is a general eruption of bubbles over the entire surface.
- ▽ The pressure difference here is related to the mean pore size. A pressure differential below the expected value would signify a damaged or faulty filter
- ▽ A modification to this test for membrane filters involves measuring the diffusion of gas through a wetted filter at pressures below the bubble point pressure (diffusion rate test); a faster diffusion rate than expected would again indicate a loss of filter integrity.

Efficiency testing of HEPA filters used for the supply of sterile air achieved by the generation upstream of dioctylphthalate (DOP) or sodium chloride particles

Chemical indicators:

- Tape with lines that change color when the intended temperature has been reached.
- Pellets in glass tubes that melt, indicating that the intended temperature and time have been reached.
- Indicator strips that show that the intended combination of temperature, time, and pressure has been achieved.
- Indicator strips that show that the chemicals and/or gas are still effective.
- Chemical indicators are available for testing ethylene oxide, dry heat, and steam processes. These indicators are used internally, placed where steam or temperature take longest to reach, or put on the outside of the wrapped packs to distinguish processed from nonprocessed packages.

Pasteurisation

Process of killing of pathogens in the milk but does not sterilize it . It was originated by Louis Pasteur and used by him for killing micro-organisms which cause undesirable fermentations in the process of making wine.

Pasteurization is now extensively used for freeing milk from disease germs. The process of pasteurization of milk consists of heating it to 60° - 65° C, (140° - 150° F.) for one half hour, followed by a rapid cooling.

In most modern dairies the raw milk is carried in pipes from large receiving tanks to the pasteurization machines. Just before entering these machines, it is passed through hot pipes which warm it to the pasteurizing temperature.

The pasteurizers consist essentially of tanks in which the milk held at the necessary temperature (usually 142° F is used) and continuously stirred for half an hour. Then the milk passes through long cold pipes, in which it is rapidly cooled, and from these pipes is carried to automatic bottling and capping machines.